

ANNEX

ANNEX III
LABELLING AND PACKAGE LEAFLET

B. PACKAGE LEAFLET

PACKAGE LEAFLET

AZOPT 10 mg/ml eye drops, suspension
Brinzolamide

Read all of this leaflet carefully before you start using this medicine.

This medicine has been prescribed for you personally. You should not pass it on to other people. It may harm them even if they have the same illness as you.

Keep this leaflet. You may need to read it again. If you still have questions after reading it, please ask your doctor or your pharmacist.

The active substance is brinzolamide 10 mg/ml.

Other ingredients: benzalkonium chloride, carbomer 974P, edetate disodium, mannitol, purified water, sodium chloride, tyloxapol.

Tiny amounts of hydrochloric acid or sodium hydroxide are sometimes added to keep acidity levels (pH levels) normal.

The marketing authorisation holder for AZOPT is Alcon Laboratories (UK) Ltd., Boundary Way, Hemel Hempstead, Herts., HP2 7UD, United Kingdom.

The maker of AZOPT is S.A. Alcon - Couvereur N.V., Rijksweg 14, B-2870 Puurs, Belgium.

1. WHAT AZOPT DOES

AZOPT eye drops are used to treat high pressure in the eye. This pressure can lead to an illness called **glaucoma**.

High pressure in the eye. Your eyeballs contain a clear, watery liquid which feeds the inside of the eye. Liquid is always emptying out of the eye, and more liquid is always being produced. If the eye fills up faster than it empties, the pressure inside the eye builds up. If it gets too high it can damage your sight.

AZOPT is one of a group of medicines for glaucoma called carbonic anhydrase inhibitors. It works by cutting down the production of liquid, which lowers the pressure in the eye. It may be used on its own or with other drops called beta-blockers, which also reduce pressure.

AZOPT is a milky liquid (a suspension) supplied in a pack containing a 5 ml or a 10 ml plastic (droptainer) bottle with a screw cap, or in a pack containing three 5 ml plastic (droptainer) bottles with screw caps. Not all pack sizes may be marketed.

2. BEFORE YOU USE AZOPT

Do not use AZOPT...

- **if you have kidney problems.**
- **if you are allergic** to brinzolamide or any of the other ingredients.
- **if you are allergic to medicines called sulphonamides.** AZOPT may cause the same allergy.
- **if you have a condition called hyperchloraemic acidosis** (too much acidity in your blood).

Ask your doctor for advice.

Take special care using AZOPT...

- **if you have liver problems.** Talk to your doctor.
- **if you have dry eyes or cornea problems.** Talk to your doctor.
- **if you wear soft contact lenses.** Don't use the drops with your lenses in. Wait 15 minutes after using the drops before putting your lenses back in. A preservative in AZOPT (benzalkonium chloride) can affect soft lenses.

AZOPT is not to be used by people under 18 years of age.

Pregnant/breast-feeding women

If you are pregnant, or might get pregnant, talk to your doctor before you use AZOPT.

If you are breast-feeding, don't use AZOPT; it may get into your milk.

Driving or using machines

You may find that your vision is blurred for a time just after you use AZOPT. Some people have found themselves sleepy or dizzy when taking AZOPT. Do not drive or use machines until this has worn off.

AZOPT and other medicines

If you are taking another carbonic anhydrase inhibitor (acetazolamide or dorzolamide, see section 1 WHAT AZOPT DOES), talk to your doctor.

Please tell your doctor or pharmacist if you are taking (or recently took) any other medicines.

Remember to mention also medicines that you bought without prescription, over the counter.

3. HOW TO USE AZOPT

The usual dose

Adults: **1 drop in the eye or eyes, twice a day** – morning and night.

Use this much unless your doctor told you to do something different. Only use AZOPT in both eyes if your doctor told you to. Take it for as long as your doctor told you to.

Only use AZOPT for dropping in your eyes.

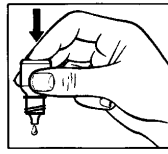
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3. HOW TO USE AZOPT (*continued*)



1



2



3

How much to use

< see side 1

- Get the AZOPT bottle and a mirror
- Wash your hands
- Shake the bottle and twist off the cap
- Hold the bottle, pointing down, between your thumb and middle finger
- Tilt your head back. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 1)
- Bring the bottle tip close to the eye. Use the mirror if it helps
- **Don't touch your eye or eyelid, surrounding areas or other surfaces with the dropper.** It could infect the drops
- Gently press on the base of the bottle to release one drop of AZOPT at a time.
- **Don't squeeze the bottle:** it is designed so that a gentle press on the bottom is all that it needs (picture 2)
- After using AZOPT, press a finger to the corner of your eye, by the nose (picture 3). This helps to stop AZOPT getting into the rest of the body.
- If you take drops in both eyes, repeat the steps for your other eye.
- Put the bottle cap back on firmly immediately after use
- Use up one bottle before opening the next bottle.

If a drop misses your eye, try again.

If you get too much in your eyes, rinse it all out with warm water. Don't put in any more drops until it's time for your next regular dose.

If you forget to use AZOPT, use a single drop as soon as you remember, and then go back to your regular routine. **Do not** use a double dose to make up.

If you are using other eye drops, leave at least 5 minutes between putting in AZOPT and the other drops.

4. POSSIBLE SIDE EFFECTS

Some people who use AZOPT may get side effects. They can be unpleasant, but most of them soon pass.

You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist.

Common side effects

One or more of these may affect up to 6 in every 100 people.

Effects in the eye: Temporary blurred vision, burning or stinging feeling just after using the drops; feeling of something in your eye; red eyes.

Effects in the body: Bitter or sour taste; headaches.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. KEEPING AZOPT

You must throw away a bottle four weeks after you first opened it, to prevent infections. Write down the date you opened each bottle in the space below and in the space on the bottle label and box. For a pack containing a single bottle, write only one date.

Opened (1):

Opened (2):

Opened (3):

Keep the drops in a safe place where children can't see or reach them.

Don't use the drops after the expiry date (marked 'Exp') on the bottle and the box.

If you have any other questions about your medicines you should ask a doctor or pharmacist.

This leaflet was last approved in xxxx 2002

FURTHER INFORMATION

For any information about these drops, please contact your local Alcon office.

België/Belgique/Belgien

SA Alcon-Couvreur NV
Rijksweg 14
B-2870 Puurs
☎ + 32 (0)3 890 27 11

Luxembourg/Luxemburg

SA Alcon-Couvreur NV
Rijksweg 14
B-2870 Puurs
Belgique/Belgien
☎ + 32 3 890 27 11

Danmark

Alcon Danmark A/S
Rødovre Parkvej 25
DK-2610 Rødovre
☎ +45 3636 3434

Nederland

Alcon Nederland BV
Avelingen-West 5
NL-4202 MS Gorinchem
☎ + 31 (0) 183 654321

Deutschland

Alcon Pharma GmbH
Blankreutestrasse 1
D-79108 Freiburg
☎ + 49 (0)761 1304-0

Norge

Alcon Norge AS
Eyvind Lyches v 10, Postboks.22
N-1300 Sandvika
☎ + 47 67 81 79 00

Ελλάδα

Άλκον Λαμποράτορις Ελλάς AEBE
Κηφισίας 18
GR-151 25 Μαρούσι
☎ + 30 210 68 00 811

Österreich

Alcon Ophthalmika GmbH
Mariahilferstr. 121b
A-1060 Wien
☎ + 43 (0)1 596 69 70

España

Alcon Cusí, S.A.
C/Camil Fabra, 58
E-08320 El Masnou-Barcelona
☎ + 34 93 497 7000

Portugal

Alcon Portugal
Produtos e Equipamentos Oftalmológicos, Lda.
Quinta da Fonte, Edifício D. Sancho I – Piso 3
Rua dos Malhões, nº 4
P-2780-730 Paço D'Arcos
☎ + 351 21 4 40 03 30

France

Laboratoires Alcon
Immeuble “Les Colonnades”
4, Rue Henri Sainte-Claire Deville
F-92563 Rueil-Malmaison Cedex
☎ + 33 (0)1 47 10 47 10

Suomi/Finland

Alcon Finland OY
PL 13
FIN-01641 Vantaa
☎ + 358 (0)9 8520 2260

Ireland

Alcon Laboratories (UK) Ltd.
Pentagon Park
Boundary Way
Hemel Hempstead
Herts., HP2 7UD
UK
☎ + 44 1442 34 1234

Sverige

Alcon Sverige AB
Box 12233
S-102 26 Stockholm
☎ + 46 (0)8 634 40 00

Ísland

K. Pétursson ehf.
Kristnibraut 29
IS-113 Reykjavík
☎ 354 - 567 3730

Italia

Alcon Italia S.p.A.
Viale Giulio Richard, 1/B
I-20143 Milano
☎ + 39 02 81803.1

United Kingdom

Alcon Laboratories (UK) Ltd.
Pentagon Park
Boundary Way
Hemel Hempstead
Herts., HP2 7UD
UK
☎ + 44 (0)1442 34 1234